QUIETSEAS - Assisting (sub) regional cooperation for the practical implementation of the MSFD second cycle by providing methods and tools for D11 (underwater noise).

D3.1. Review of risk-based approaches and frameworks for D11C2

This project has received funding from DG Environment of the European Commission within the "DG ENV/MSFD 2020 call" under grant agreement No. 110661/2020/839603/SUB/ENV.C.2.

Document information	
Deliverable	Review of risk-based approaches and frameworks for D11C2
Document Number	QUIETSEAS – D3.1
Delivery date	29th October 2021
Call	DG ENV/MSFD 2020 call
Grant Agreement	No. 110661/2020/839603/SUB/ENV.C.2

No	Participant organization name	Participant short name	Country
1	Centro Tecnológico Naval y del Mar	CTN	Spain
2	Permanent Secretariat of the Agreement on the Conservation of Cetaceans of the Black Sea, Mediterranean Sea and Contiguous Atlantic Area	ACCOBAMS	Monaco
3	Service hydrographique et océanographique de la marine	Shom	France
4	Politecnico di Milano-Department of Civil and Environmental Engineering	POLIMI-DICA	Italy
5	Hellenic Centre for Marine Research	HCMR	Greece
6	Inštitut za vode Republike Slovenije/Institute for water of the Republic of Slovenia	IZVRS	Slovenia
7	Specially Protected Areas Regional Activity Centre	SPA/RAC	Tunisia
8	Maritime Hydrographic Directorate	MHD	Romania
9	Department of Fisheries and Marine Research	DFMR	Cyprus
10	International Council for the Exploration of the Sea	ICES	Denmark

Dissemination level	
PU: Public	
PP: Restricted to other programme participants (including the Commission Services)	
RE: Restricted to a group specified by the consortium (including the Commission Services)	
CO Confidential, only for members of the consortium (including the Commission Services)	X

Date	Revision version	Company/Organization	Name and Surname
01/09/2021	Draft0	CTN	María Bernabé
19/10/2021	Draft0	CTN	Noelia Ortega, María Bernabé
22/10/2021	Draft 1	ACCOBAMS	Alessio Maglio
05/11/2021	Reviews provided	ICES, HCMR, IZVRS, SHOM, POLIMI	Neil Holdsworth, Aris Prospathopoulos,

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30/10/2021	Draft 2	ACCOBAMS	Alessio Maglio
30/10/2021	Final version	CTN	María Bernabé

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Abstract

This document is the Deliverable "D3.1. Review of risk-based approaches and frameworks for D11C2 (29th October 2021)" of the QUIETSEAS project funded by the DG Environment of the European Commission within the call "DG ENV/MSFD 2020 call". This call funds projects to support the implementation of the second cycle of the Marine Strategy Framework Directive (2008/56/EC) (hereinafter referred to as MSFD), in particular to implement the new GES Decision (Commission Decision (EU) 2017/848 of 17 May 2017) laying down criteria and methodological standards on Good Environmental Status (GES) of marine waters and specifications and standardised methods for monitoring and assessment, and repealing Decision 2010/477/EU) and Programmes of Measures according Article 13 of the MSFD. QUIETSEAS aims to support the practical development of the second implementation cycle under the MSFD for D11 (underwater noise).

This document presents a review of Risk Assessment approaches as a basis for the establishment of a risk-based assessment of continuous noise (MSFD-D11C2).

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List of Abbreviations

CTN	Centro Tecnológico Naval y del Mar
ACCOBAMS	Permanent Secretariat of the Agreement on the Conservation of Cetaceans of the Black Sea, Mediterranean Sea and Contiguous Atlantic Area
DFMR	Department of Fisheries and Marine Research
IZVRS	Inštitut za vode Republike Slovenije/Institute for water of the Republic of Slovenia
HCMR	Hellenic Centre for Marine Research
UM	University of Malta -The Conservation Biology Research Group
POLIMI-DICA	Politecnico di Milano-Department of Civil and Environmental Engineering
SPA/RAC	Specially Protected Areas Regional Activity Centre
ICES	International Council for the Exploration of the Sea
Shom	Service hydrographique et océanographique de la marine
MHD	Maritime Hydrographic Directorate
MSFD	Marine Strategy Framework Directive
GES	Good Environmental Status
MS	Member States
MED	Mediterranean Sea
BS	Black Sea
CA	Competent Authority
NR	National representative
SO	Specific Objective
TB	Thematic Block

1. Introduction

The QUIETSEAS Project is funded by DG Environment of the European Commission within the call "DG ENV/MSFD 2020". This call funds MSFD development, in particular, the preparation of the next 6-year cycle of implementation. The QUIETSEAS project aims to enhance cooperation among Member States (MS) in the Mediterranean Sea Region (MED) to implement the third Cycle of the Marine Directive and in particular to support Competent Authorities and strengthen cooperation and collaboration in the Mediterranean Sea and Black Sea regions.

This deliverable is the result of work done on Activity 3. Analysis of the practical implementation of the Assessment Framework for Continuous Noise (D11C2) provided by TG Noise, and support the achievement of the following specific objectives of the project:

- Specific objective 1 (SO1): To identify relevant indicators for criterion D11C2 (Anthropogenic continuous low-frequency sound in water).
- Specific objective 2 (SO2): To promote the consolidation of relevant indicators for D11 and support the operationalisation of indicators on the state, pressure and impacts of underwater noise in close coordination with TG Noise.
- Specific objective 3 (SO3): To promote harmonisation of regional work on threshold values with TG Noise recommendations.

The project is developed by a consortium made up of 10 entities coordinated by CTN and it has a duration of 24 months starting on 1st February 2021.

2. Background

Article 1(2b) of the MSFD (2008/56/EC) establishes the following specific objective:

- **Prevent and reduce inputs in the marine environment, with a view to phasing out pollution as defined in Article 3(8), so as to ensure that there are no significant impacts on or risks to marine biodiversity, marine ecosystems, human health or legitimate uses of the sea.**

While the overarching goal is the achievement and maintenance of the Good Environmental Status, the concept of risk is already introduced in the MSFD objectives themselves, and although the Directive does not explicitly mandate MS to carry out risk assessments, Article 14(4) clearly states that MS may not take further steps, except in respect of the initial assessment described in Article 8, if there are no significant risks to the marine environment.

This means that, in practice, it is expected that MS focus, via Articles 9, 10, 11 and 13, on those pressures and areas presenting higher risks.

This document presents a review of approaches for a risk-based assessment and a proposal for the establishment of a risk-based assessment for continuous noise in the Mediterranean and Black Sea areas (MSFD-D11C2).

2.1. Synthesis of most relevant approaches for risk assessment

The determination and assessment of GES for D11, as established by the GES decision, relies to a great extent on thresholds yet to be determined. It is now widely acknowledged that risk management processes provide several opportunities to set thresholds for underwater noise and offer a framework to deal with uncertainties related to this topic. Thresholds should ideally be based on dose-response relationships indeed and indicate values above which risk is deemed not acceptable (Fig. 1).

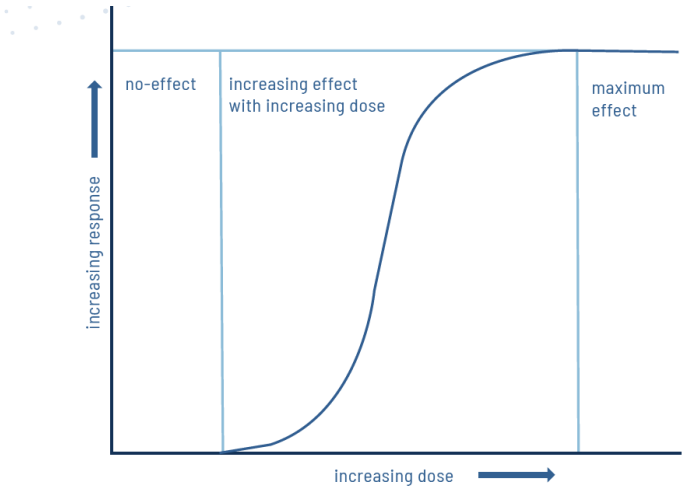

Figure 1. Dose-response curve providing a solid basis for threshold setting

However, other possibilities are offered by a risk assessment process in order to cope with lacking information and areas of uncertainty.

Based on the definition of the **US Environmental Protection Agency (EPA)**, risk assessment is an exercise performed to evaluate the likelihood of adverse effects occurring as a result of exposure to stressors/hazards (Add reference). In ecological terms and at the ecosystem scale, this may be translated as the probability that there will be a significant adverse effect on a particular ecosystem as a whole, for example in an assessment area that is not too large and thus manageable.

As a practical example of this definition, we may consider cetacean populations as the ecological flagship indicating the status of the ecosystem health. Therefore, as far as adverse effects are concerned, they can be indicated as one of the known impacts induced by continuous noise on cetaceans, for example the loss of communication space due to masking of biological signals or behavioural reactions such as displacement, change in diving and feeding patterns etc. Based on EPA definition, risk assessment would mean the following:

- **Evaluating the probability that there will be an adverse effect on target population (i.e. cetaceans) such as loss of communication space or any behavioural response which may hamper their survivorship as a result of exposure to continuous noise during the assessment period.**

However, not only the likelihood that an adverse effect will occur it matters, but also the magnitude of such an effect on populations. In this case, we would follow the definition of Risk from the **ISO31000:2018 standard**:

- **Risk = [likelihood that an adverse effect will occur] × [magnitude of consequence]**

This definition combines the concepts of likelihood and magnitude of an adverse effect and appears flexible enough to be applied to continuous noise and to the many sources of uncertainty related to the adverse effects on cetacean populations that may be caused by continuous noise.

2.2. Framework to manage risk in the MSFD

A broad view of risk management applied to the MSFD is proposed in the Deliverable 2.3 of RAGES project (Add reference).

Figure 2. Risk management framework proposed in Deliverable 2.3 of RAGES project.

With regards to Fig. 2, several works address the Step 1 (Risk Context), including work from TG Noise (Claussen et al., 2011; Dekeling et al., 2014; Tasker et al., 2010; Van der Graaf et al., 2012) and those produced by projects funded by DG ENV (e.g., QUIETMED 2 Deliverable 5.1). Moreover, Deliverable 2.3 of RAGES project discusses different models potentially useful for Step 2 (Risk Identification) and makes proposals for application of such models to D11. Furthermore, Step 5 (Risk treatment) deals especially with targets and measures and therefore is not addressed in this report. In the end, the main element of risk management which is still lacking for continuous noise is the Step 3 – Risk Analysis, which is the focus of this report. Once this point has been addressed, there will be a basis to develop thresholds for GES assessment, which is the topic of Step 4 (Risk Evaluation), and also Step 5 (Risk treatment) would benefit from results from Step 3 and 4.

2.3. Analysis of risk-based approaches and frameworks in the MSFD

An example of Risk Assessment in Toxicology and analogy with continuous noise is given here. The stepwise process described below in Table 1 presents the elements of a generic risk assessment with examples in eco-toxicology (a discipline which extensively uses ecological risk assessment related to toxic substances and pollutants) and its possible analogies for D11C2 assessment.

N	Steps	Examples in Ecological Risk Assessment (Eco-Toxicology)	Possible analogywith a risk-based assessment of D11C2
1	Definition of the hazard i.e. the description of the hazard and the ecological endpoint of the related danger, the source of this danger and the environment where it exists	Agriculture pesticides drifts causing river fish kills	Continuous noise levels causing behavioural disruption of masking
2	Assessment of the exposure an estimate of contact with or dose to ecological endpoint	Pesticide concentrations in river fish habitats and duration of exposure to such concentrations	Extent and duration of exposure to continuous noise
3	Assessment of the magnitude of the effects	Expressed in terms of dose-response curve, predicts the mortality of fish as function of the received doses (e.g. median lethal concentration - LC50)	The amount of reaction and effect on populations, e.g., the proportion of population affected, a change in a physiological parameter such as auditory capabilities, a change in population parameters such as abundance or birth rate, or ecological parameter such as the communication space or habitat exclusion However, no such dose-response curves are sufficiently known for wild cetaceans (e.g. PCoD models and similar) and therefore the prediction of population effects based on received noise levels remain a challenge.
4	Characterisation of the risk/result of assessment	The likelihood that hazard concentrations in rivers are above thresholds of effects (e.g. 96h-LC50) **Example of risk formulation**: it is expected (= high probability, may be quantified) that there will be X% of fish mortality in rivers close to farms	The likelihood that continuous noise is above levels inducing onset of adverse effects on cetaceans. The likelihood may be expressed as a function of the spatial and temporal overlap between noise and populations of marine species (extent of the exposure).
5	Management of the risk	Measures for reducing risks, not addressed in this document	

Table 1. Risk-assessment framework, taken form examples in toxicology, and its possible analogies to D11C2 assessment.

In the MSFD implementation, a risk-based approach can be used in the context of the GES Decision and implementation of Articles 9, 8, 10, 11 and 13, including examples.

Article 9(3) –criteria and methodological standards for GES (GES Decision).

The GES Decision makes explicit reference to the risk-based approach and sets out criteria for good environmental status in relation to the predominant pressures and their impacts and on state elements which can best reflect these pressures and impacts (Section 7: Background document for the Marine Strategy Framework Directive on the determination of good environmental status and its links to assessments and the setting of environmental targets- SWD (2020) 62 final).

For example, under Descriptor 3, the Maximum Sustainable Yield values used to assess the status of the commercially-exploited species, are values above which the risk from fishing of overfishing is considered high,

Moreover, to assess both D8 and D9, thresholds have been established for a number of contaminants through quantitative toxicological risk assessments

2.4. Analysis of the Assessment Framework for Continuous Noise at Regional Convention level (all regions)

- **NETCCOBAMS maps**

NETCCOBAMS. Since 2019, the NETCCOBAMS platform[1] includes an area where acoustic risk maps for cetaceans are shown. The methodology has been developed specifically for achieving conservation objectives of the ACCOBAMS agreement and formalization of this methodology is ongoing. A summary is provided here:

- Habitat maps are computed for cetacean species; the maps show an index ranging from 0 to 1 where each value corresponds to a colour shade. The index tells us about how much probability there is to find animals in the different areas of the map (0 = low, 1 = high)
- Shipping noise maps are generated to show mean, median and 95th percentile Sound Pressure Level (SPL) in the 1/3 octave bands centred at 63 Hz and 125 Hz.
- For the spatial overlap computation, the following indicators are taken:
  - The 95th percentile of shipping noise for the summer period (July-August), to highlight the areas with highest values during the 5% of time during those two summer months
  - Highly suitable portions of the habitat of fin whale, Cuvier's beaked whale and sperm whale (i.e., index > 0.75)
- The spatial overlap intersects habitat areas with index higher than 0.75 and 95th percentile SPL values higher than thresholds for auditory impairment. The overlap is shown in red (Fig. 3) and orange threshold (Fig. 4), according to different noise thresholds used.

[1] NETCCOBAMS is currently online at the following URL: accobams.sinay.fr; login and password can be requested by sending an email at the ACCOBAMS Secretariat

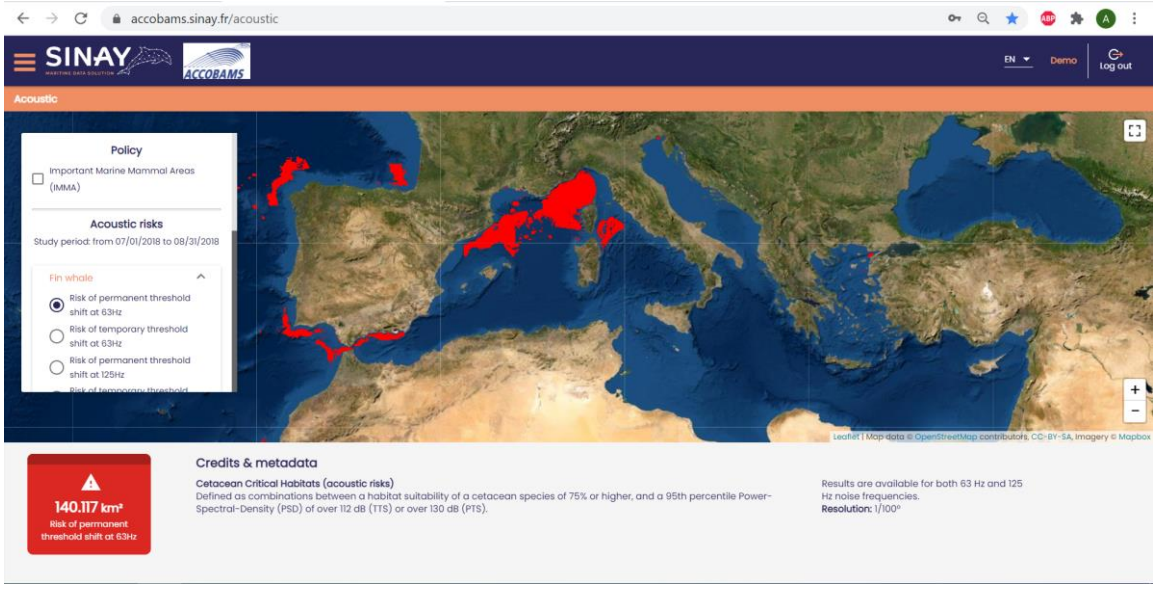

Figure 33. Acoustic risk areas produced by levels exceeding NOAA PTS thresholds (2019) on fin whale habitats (NETCCOBAMS platform)

Figure 44. Acoustic risk areas produced by levels exceeding NOAA TTS thresholds (2019) on fin whale habitats (NETCCOBAMS platform)

➔ HELCOM HOLAS

HELCOM guidelines for continuous noise are based on BIAS project (Baltics seas Information on the Acoustic Soundscape) and JOMOPANS project (Joint Monitoring Programme for Ambient Noise North Sea). These project assessment frameworks provided coverage of the frequencies used by most marine species, to allow flexible approaches to subsequent analysis, including auditory weighting to reflect the risk of impact on marine species.

➔ **BIAS**

The BIAS project exclusively deals with continuous low frequency sound (ambient noise) with the aim to establish a regional implementation plan (a regional programme for monitoring underwater ambient noise in the Baltic Sea) for the associated MSFD indicator. This implied developing regional standards, methodologies and tools to enable cross-border handling of acoustic data and associated results for the Baltic Sea. BIAS also put the implementation plan into practice, with many valuable experiences regarding to the different steps in the extensive monitoring effort.

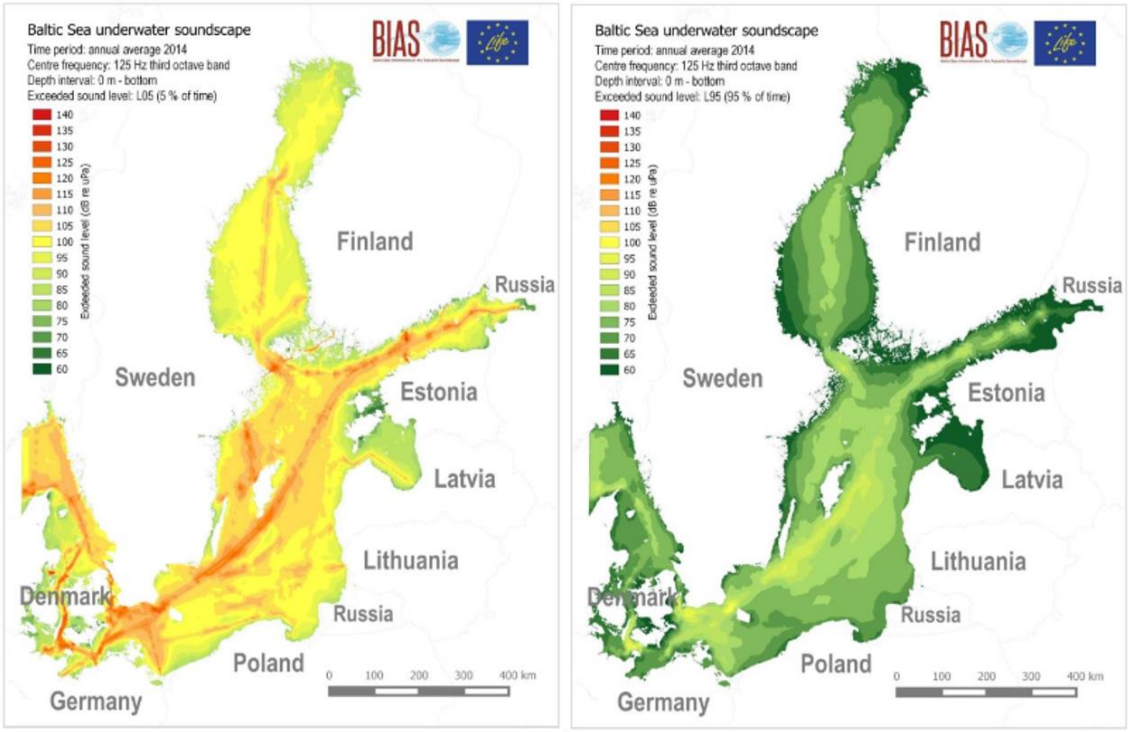

Figure 9. The modelled annual average soundscape for 2014, for the 125 Hz third octave band and over the full depth. (Left figure) Noise levels occurring occasionally (5%of the year; L05), and (right figure) noise levels occurring regularly (95% of the year; L95).

➔ **JOMOPANS**

The project started in January 2018 and ended in June 2021. Implementation plan was to advise the Jomopans consortium to the marine managers of the North Sea countries on how to implement regular monitoring of ambient noise. The Jomopans assessment framework for ambient noise contains a stepwise approach. A summary is provided below:

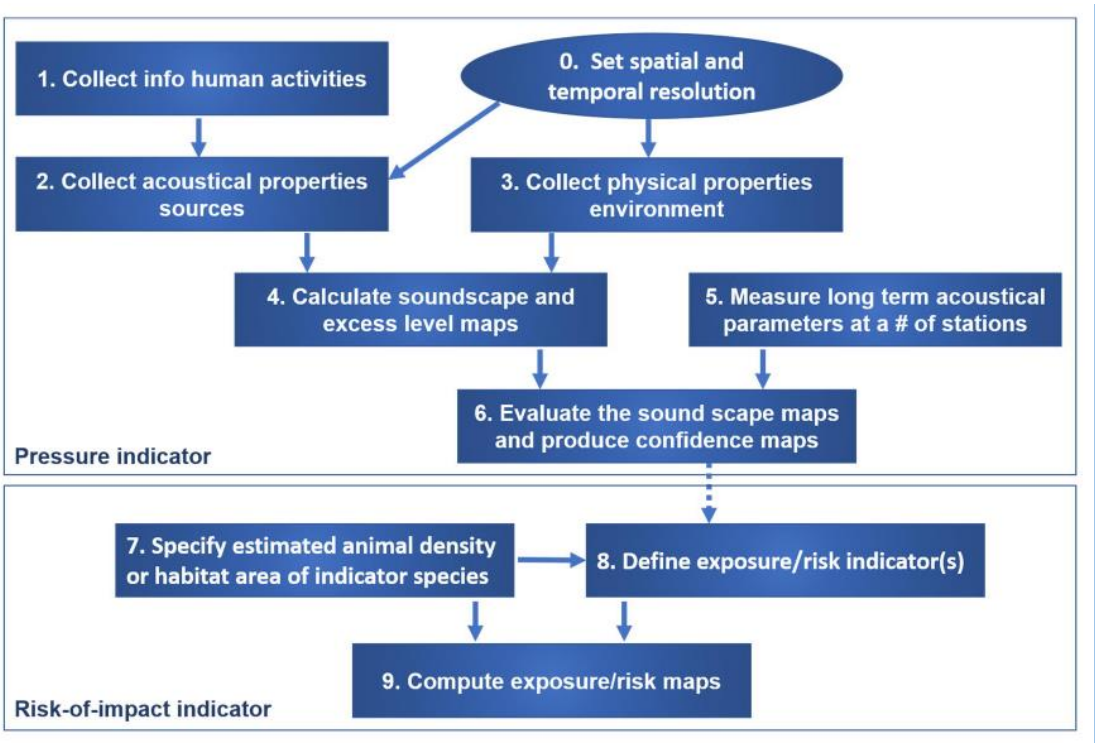

Figure 10. Framework ambient noise sound indicators (from Van Oostveen et al., 2020).

The methodology has been developed to link pressure indicator to risk-of-impact indicator throughout several steps:

- Calculate soundscape and excess level maps from acoustical models for sound from natural sources and propagation models for sound propagation of continuous sound.
- Measure long term acoustical parameters at a number of stations to obtain statistical parameters of the Sound Pressure Level and thus validate the modelling.
- Evaluate the soundscape maps and produce confidence maps.
- Use density estimation data of animals if available and appropriate, otherwise, use habitat area of indicator species.
- Compute exposure and risk map to one exposure curve relative to the quantitative assessment of confidence in the risk values derived.
- Compute exposure and risk indicators for each region.

The major product of the programme is a (set of) common regional soundscape map(s). These maps give a seamless picture of the noise distribution on the North Sea and show no discontinuities along national boundaries. A summary is provided here:

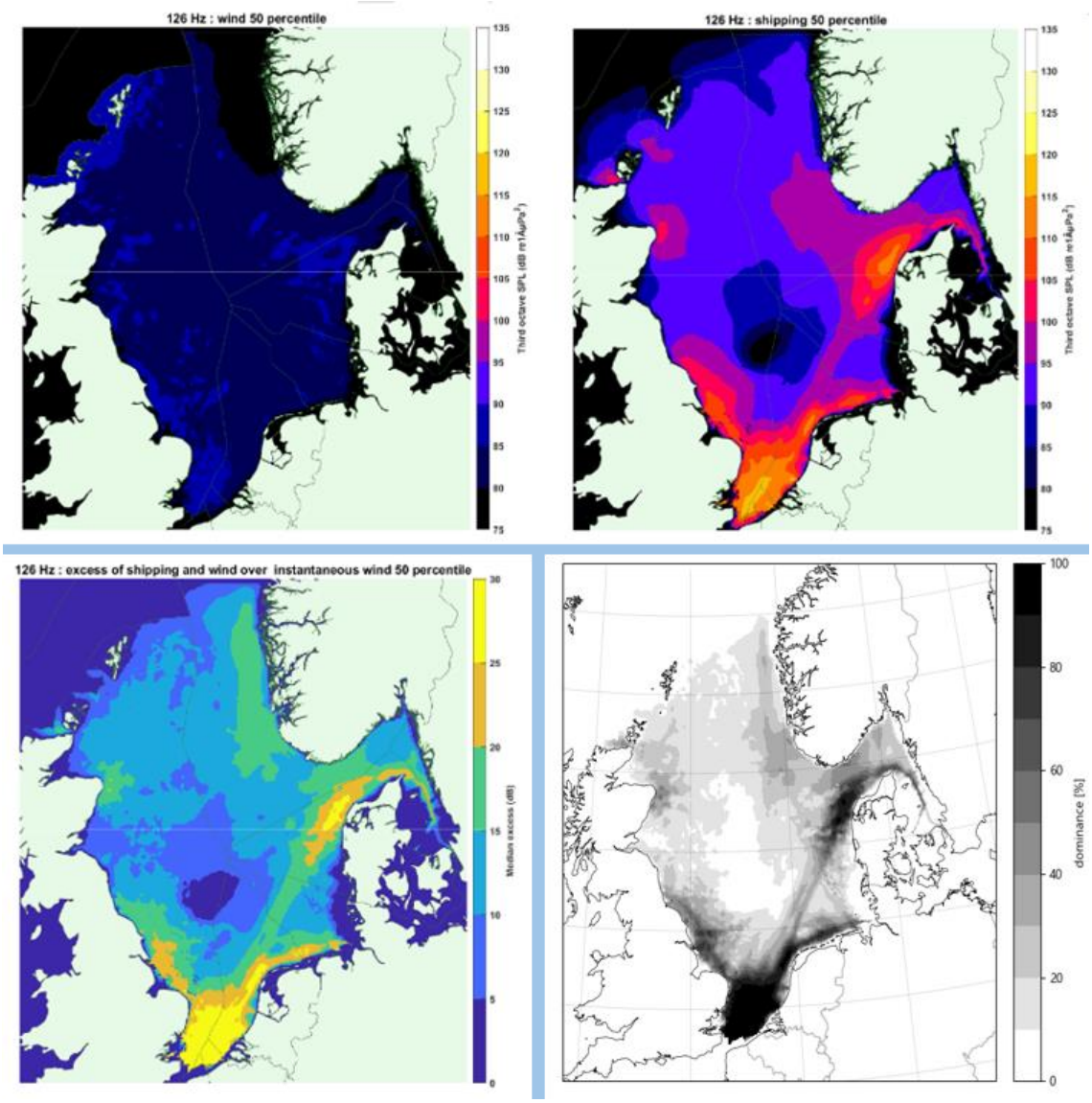

Figure 11. Median Background Sound Level, 126 Hz band (wind) (Left head); Median Sound Pressure Level by shipping, 126 Hz band (Right head); Median Excess Level, 126 Hz band (Left bottom); Dominance maps for a cut off level of 20 dB of the Excess Level (Right bottom).

➔ JONAS

JONAS addresses threats to biodiversity from underwater noise pollution on sensitive species in the NE Atlantic by streamlining ocean noise monitoring and risk management on a transnational basis. States need a consistent way to resolve this common transboundary challenge. JONAS will develop and pilot a noise-monitoring platform, harmonise technical approaches to MSFD and MSP requirements and promote the adoption of quieter operational practices among users of the northeast Atlantic marine space.

- **PIAQUO**

The European Life-PIAQUO project aims to reduce the impact of maritime traffic noise on marine ecosystems as required by European regulations. It brings together ten partners. The aim is to develop quieter ships, to develop tools for estimating in real time the noise radiated by the ship, and to furnish maps of marine ecosystems in the transit area to stakeholders in order to help adapting the maritime traffic.

3. Methodological framework for regional and subregional risk-based assessment for continuous noise in the Mediterranean and Black Seas.

3.1. General framework for assessment

Based on the background described in Chapter 2, the risk will be addressed as a combination of two components:

- The likelihood of an adverse effect to occur because of exposure to continuous noise
- The magnitude of the adverse effects of such exposure to continuous noise on populations

Figure 5 below illustrates the link between the two components.

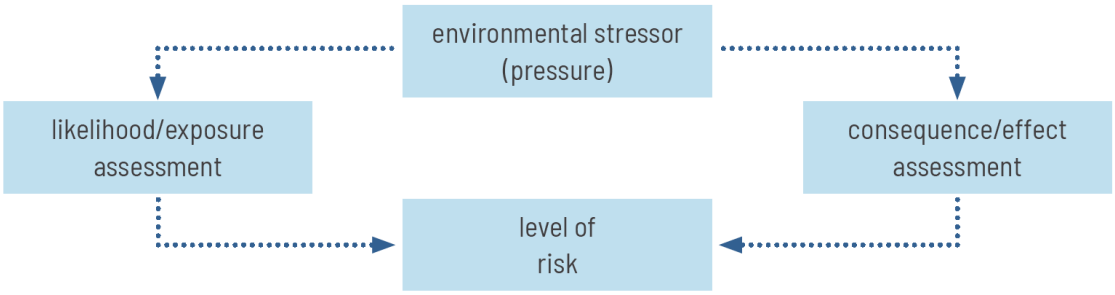

Figure 55. General ISO3100-based framework for Risk Assessment (RAGES D2.3).

As a first step, **to assess the likelihood** of an adverse effect to occur **we need to know the exposure**, i.e., to what level cetacean populations are exposed to continuous noise potentially causing negative effects. This may simply be interpreted as the spatial overlap between potentially harmful noise levels and areas used by cetaceans. Also, the time component, i.e., the duration of exposure, must be considered. This part of the work is also named "exposure assessment". If we know enough about biology/bioacoustics of a target species (target population) we may therefore understand if such adverse effects as behavioural responses and the masking of biological sounds occurred due to exposure to continuous noise. With such a basic approach, **the level of risk could be considered proportional to the exposure** based on the following assumption: **the higher the level and the duration of exposure, the higher is the likelihood of adverse effects** on target populations.

However, using exposure only to assess the level of risk does not inform on the magnitude of such effects on populations. In that respect, the magnitude of effect on populations might be the proportion of population affected, a change in physiological parameters such as auditory capabilities, a change in population parameters such as

abundance or birth rate, or any other ecological parameter (endpoint) such as the communication space or habitat exclusion.

As far as data are (or become) available about effects on cetacean populations, the magnitude of effects could be included in the assessment exercise. Such knowledge is highly useful if it is expressed as dose-response curves. The dose received by the target population is the concept studied during the exposure assessment (see above in this section) and it includes the following components: the area covered by levels high enough to induce negative effects, and the duration of exposure over that area. The response is the kind of reaction on populations that we want to study in relationship to such exposure to continuous noise. If we are able to build a function linking dose and response, then a dose-response curve will allow to calculate how much a population is affected by continuous noise: % of population with auditory impairment, trends in abundance, extent of habitat exclusion, change in birth rate, mortality, etc. However, such dose-response curves are still unknown for most cetaceans.

Fig. 6 illustrates conceptually the components of a risk assessment, with two examples of adverse effects on populations: loss of communication space due to masking of biological sounds, and the avoidance of an area exposed to high noise levels (behavioural reaction).

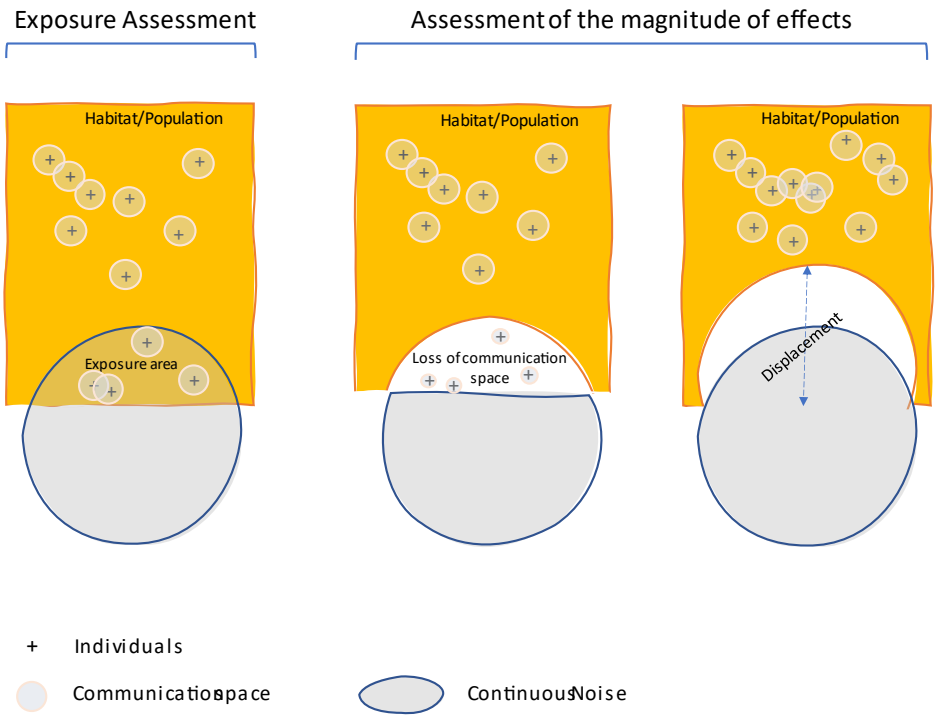

Figure 66. Conceptual view of exposure assessment (left) and assessment of the magnitude of effects (right) on habitats/populations. (Source: adapted from QUIETMED2 Deliverable 4.1).

3.1.1. Technical specifications

3.1.1.1. Metrics

This section indicates metrics involved in the risk-based assessment that would allow setting thresholds. Several possible indices are proposed to this end, based on:

- The area affected and the duration of exposure to continuous noise of cetacean habitats (Exposure Indices, EIs).
- The magnitude of adverse effect due to continuous noise on cetacean populations

The exposed area is calculated as the proportion of a habitat affected by continuous noise exceeding a specific noise level (% of habitat exposed) during a specific time frame (assessment period). The duration of exposure is the duration in days of the noise exposure over the assessment period (% of time that habitat is exposed within the assessment period).

The amount of adverse effects due to continuous noise on cetacean populations can be one of the following: communication space loss due to masking of biological signals, change in the feeding/chasing time, proportion of population with auditory impairment, and more. No clear recommendation is given on such parameters because of the many uncertainties existing and because the way to address them may be highly variable. are This is in line with TG Noise rationale still under development during the QUIETSEAS project.

3.1.1.2. Ecological target for assessment of GES

It is proposed that the habitat definition for criterion D11C2 be consistent to the definition resulted from the two meetings held during QUIETMED-2 (June 2019 in Monaco and January 2020 in Cartagena, Spain) with members of the Joint ACCOBAMS/ASCOBANS/CMS Noise Working Group (JNWG) and members of the QUIETMED-2 consortium. The definition issued from those meetings was the predicted suitable habitat (potential habitat) of selected species, modelled by using physiographical characteristics as covariates (e.g. bathymetry and slope; see Azzellino et al. 2012).

However, it is important to consider that other biological characteristics can contribute to the species habitat selection. As an example, the continental shelf might become an important habitat for a species only when upwellings are occurring, which are known to be seasonal. One way to address seasonality and other biological aspects may be selecting relevant assessment areas (i.e. upwelling areas) and periods (i.e. summer period).

3.1.1.3. Applicability to subregions

The framework is applicable to all subregions of the Mediterranean Sea and the Black Sea. However, important differences may be applied in some of the points of the overall procedure described above. Especially, the way sound propagation modelling is applied may vary form a subregion to another, according to specificities of the Mediterranean and Black Sea. This topic is tackled in Activity 4 of the QUIETSEAS project.

3.1.1.4. Assessment scales of the framework

Three assessment "areas" and corresponding levels of assessment can be distinguished and applied:

- **The Grid Cell.** This level addresses the smallest spatial unit over which it is practicable to evaluate the condition of the area covered by the Cell. Continuous noise distributions should be computed for each of these units and the acoustical parameters are described by a single quantity, which will vary in time. A noise level threshold (for example for the onset of adverse effects) are applied to evaluate their condition, i.e., understand if the noise level in a grid cell exceeds such a threshold. Grid Cells are the initial step in the assessment, before proceeding to cell aggregation to larger assessment areas (e.g. Habitat, MRU).
- **Habitat.** The habitat of one or more selected species (e.g., a cetacean species) is the focus of the assessment (see also Section 3.2.1.2). The choice of the habitat takes into account factors such as the conservation status of a species, rarity, isolation, etc. The assessment at the habitat scale considers how many grid cells show exceedance of spatial and temporal thresholds.
- **Marine Reporting Units (MRUs).** This is the administrative level at which EU MS report about the status of marine environment. According to SWD (2020)62, Section 5.4, MRUs are termed as the specific areas of each region or subregion to which each GES assessment applies. A judgment is made on whether GES has been achieved for a specified element or Descriptor and the extent to which GES has been achieved is reported. It may be wider, coincide, or be smaller than a habitat.

3.2. Implementation

3.2.1. Assessment criteria and targets

Assessment of GES against targets or desired state can be on a qualitative or quantitative basis.

The main approaches for target setting are:

1. **Directional/trend-based;**
2. **Baseline values against which to measure change;**
3. **Thresholds.**

The latest MSFD Commission Decision (2017/848/EU) requires that threshold values (point 3) should be set by Member States through cooperation at Union level, in relation to a reference condition (common element with point 2), taking into account regional or subregional specificities, such that populations of marine animals are not adversely affected by anthropogenic continuous sound sources. The methodology presented here provides a basis for defining Threshold Values (TVs), according to the exposure of selected species populations to continuous sound and, therefore, their risk of adverse effects. The methodological implementation to establish TVs and calculating Exposure Indices (EIs) is proposed in Activity 5 of QUIETSEAS and is not described here in detail.

Briefly, there is a preference for using the same approach of setting TVs with the one used for the assessment framework for impulsive noise in the Mediterranean Sea Region (see QUIETMED2, D6.2):

- Spatial and temporal thresholds are set;
- If the spatial threshold is exceeded, the temporal threshold is considered;
- The use of combined spatial and temporal thresholds can be used for assessing GES.

3.2.2. GES spatial assessment considerations

The geographical scope of the assessment is driven by the estimated distribution of the indicator species and/or their recognised habitat. For some species, the regional scale may be appropriate, while for others, smaller geographical scales (subregions or even national waters) will be applicable. TG Noise recommends that habitats and indicator species are considered at MS level. When habitats expand to more than one MS, then habitats and indicator species are considered at regional/subregional level. Moreover, geographical specificities in particular marine areas of the Mediterranean and Black Seas must be considered (e.g., Adriatic Sea, Aegean Sea, etc.).

One option for assessing GES as regards the link between habitats and MRUs could be to consider the "*One Out All Out*" approach at all assessment scales, meaning that if one habitat does not reach GES, all the MRU is not at GES. However, this approach may be unsuitable for heterogeneous areas (such as the Aegean-Levantine subregion). As regards TG Noise, the difficult point of linking habitats and MRUs for GES assessment has been left for DL4 (Options for thresholds values for continuous noise), which is expected to be finalised in the last quarter of 2022. In the context of QUIETSEAS project, potential solutions will be proposed in the deliverables of other Activities (Activities 4, 5 and 6).

3.2.3. Monitoring considerations

According to TG Noise recommendations, acoustic monitoring can be implemented through either modelling or measurements or a combination of both. All options present challenges in their implementation. Models should reflect the capacity to adequately simulate the shipping activity or other relevant continuous sound sources, and the

natural soundscape and validation of their results is required through direct measurements to assure its credibility. On the other hand, the sole use of measurements is adequate only when the location(s) are representative for the whole assessment area or under special conditions (e.g. areas of low shipping density).

Although modelling for the Mediterranean and Black Seas is challenging (more information will be provided in Activity 4), there are currently relevant models running (see e.g., NETCCOBAMS platform in Section 2.5). However, it seems that the national/regional programmes are not adequate to cover the needs for measurements, either for validation of the models or for characterising the acoustic status of assessment areas, thus rendering further regional initiatives and efforts highly desirable.

As regards biodiversity information, coordination with initiatives related to MSFD Descriptor 1 and Ecological Objective 1 under the Ecological Approach (EcAp) of UNEP/MAP Barcelona Convention) is also highly desirable. In addition, there may be a need for strong regional coordination to regularly implement programmes such as the ACCOBAMS Survey Initiative (2018) to obtain distribution and abundance data of cetacean populations by using a common protocol throughout the Mediterranean and Black Seas.

3.2.4. Reporting

To achieve international coordination between MS in monitoring and assessment, agreements have to be made on reporting of the results. It should be also clear how the results will be fed into informing management measures. Reporting will consider the MSFD and EcAp process cycles as well as ACCOBAMS needs in terms of monitoring, assessment and management of threats to cetaceans.

3.2.5. Further development

The methodological assessment framework for continuous noise proposed in this Deliverable shall be submitted for adoption to relevant processes in the Mediterranean Sea (ACCOBAMS and the Barcelona Convention) and Black Sea (Bucharest Convention), according to their agenda and timeline.

4. A Risk-based approach for assessment of continuous underwater noise

The assessment framework for continuous noise follows a risk-based approach as it links the exposure to noise levels to the potential impact on one or more species. By assessing noise distribution and levels on the habitat of a species potentially adversely affected by noise, the framework assesses potential risk and supports the identification of those areas where it may be more important to tackle noise. If it instead considered only the distribution and intensity of the pressure regardless of species distribution/presence and sensitivity to noise (noise level at which an adverse effect is assumed to happen), the assessments could lead to pointless measures.

Therefore, for assessing continuous noise, a framework based on ecological risk assessment is proposed and the ISO definition of Risk (ISO 31000:2009) used as basis:

RISK = LIKELIHOOD of adverse effects x CONSEQUENCE/MAGNITUDE of impact

This definition expresses the level of risk as the combination of the likelihood of an adverse effect and the magnitude of the impact. The level of risk is assessed qualitatively, semi-quantitatively or quantitatively according to the available data and knowledge.

This is also the most common definition in all the fields using Risk-based assessment, (e.g., toxicological risk, natural disaster risk, and obviously environmental risk) and it appears flexible enough to be adapted also to noise.

In environmental terms, Risk Assessment is an exercise performed to evaluate the likelihood and the magnitude of adverse effects occurring on ecological endpoints resulting from exposure to stressors/hazards (Suter II, Glenn W, 1992, 2016).

To turn this into practice, we may consider **noise-sensitive species (such as cetaceans) and factors affecting population parameters as ecological endpoints, and of course continuous noise as the stressor/hazard**

The adverse effects (endpoints) we refer to are for example hazardous behavioural responses (e.g. displacement from a feeding habitat) and the masking of biological sounds due to the continuous noise background levels which may hamper the species sociality and behaviour.

The magnitude is the amount of such reactions and the corresponding effect on populations, e.g., the proportion of population affected, a change in a physiological parameter such as auditory capabilities, a change in population parameters such as abundance or birth rate, or ecological parameter such as the communication space or habitat loss.

The likelihood of effects depends on the exposure of the vulnerable species to potentially adverse noise levels, where “exposure” can be expressed in several ways, including the potential habitat occupation and the estimated abundance in the area.

It is known that establishing a quantitative link between exposure and magnitude of population effects remain a challenge with regards to underwater noise. However, the Risk Assessment approach is flexible enough to allow for different levels of assessment: qualitative, semiquantitative and quantitative, according to availability of data and knowledge; and at different stages of the risk analysis: exposure assessment, effects assessment.

In conclusion, to analyse risk two main aspects must be considered: the likelihood of a reaction event or interaction between an ecological target (population) and the pressure (noise), and the magnitude of consequences of that event or interaction for the target population (assessment endpoints):

- First, the spatial, temporal distribution and/or intensity of the relevant anthropogenic activities and associated pressure(s) are characterized and the resulting overlap with the ecosystem elements are estimated. This exposure might be used to quantify the level of risk by assuming that "the more the exposure the more the likelihood of adverse effects to occur".
- Further, the magnitude of impact considering the demographic, biological and/or ecological characteristics of the target groups is assessed qualitatively or semi quantitatively, unless a quantitative approach is possible and dose-response relationships or other method to quantify the adverse effects from a given pressure on the ecosystem elements are available.

5. References

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